DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB

Display Date 6-17-02

Publication Date 6-18-02

Certifier R. LEDESMA

Food and Drug Administration

[Docket No. 99D–5199]

Medical Devices; Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery." This guidance is intended to provide guidance on the preclinical testing recommended for resorbable adhesion barrier devices used in abdominal and/or pelvic surgery. This guidance is being issued to finalize the previous draft version issued on December 16, 1999.

DATES: Submit written or electronic comments concerning this guidance at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled "Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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FOR FURTHER INFORMATION CONTACT: Joyce M. Whang, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document is intended to provide guidance on the preclinical and clinical testing recommended for resorbable adhesion barrier devices used in abdominal and/or pelvic surgery. It was developed jointly by the Division of General, Restorative and Neurological Devices, and the Division of Reproductive, Abdominal and Radiological Devices. The final version of this guidance supersedes the draft version published in the **Federal Register** on December 16, 1999 (64 FR 70264). The comment period for the draft guidance ended on March 15, 2000. A meeting of the Obstetrics and Gynecology Devices Panel was held on January 25, 2000, to discuss the draft version of this guidance.

Comments received on the draft guidance generally addressed the use of adhesion reduction as a surrogate endpoint for clinical endpoints such as fertility, pelvic pain, and small bowel obstruction. Several respondents stated that adhesion reduction itself should be considered an endpoint that provides a clinical benefit to the patient irrespective of other clinical outcomes such as those mentioned above. The agency believes that whether adhesion reduction is considered a surrogate or clinical endpoint, it is valid as a study endpoint so long as the adhesion reduction measured provides some reasonable assurance that the adhesion barrier will provide clinically significant results.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on resorbable adhesion barrier devices used in abdominal and/or pelvic surgery. It does not create or confer any rights for or

on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

In order to receive "Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery" via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1356) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

You may obtain a copy of the guidance from the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. You may access the CDRH home page at http://www.fda.gov/cdrh. You may search for all CDRH guidance documents at http://www.fda.gov/cdrh/guidance.html. Guidance documents are also available on the Dockets Management Branch Web site at http://www.fda.gov/ohrms/dockets.

IV. Comments

You may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this guidance at any time. You should submit two copies of any comments. Individuals may submit one copy. You must identify comments with the docket number found in brackets in the heading of this document. The guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 5/31/02

May 31, 2002.

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

[FR Doc. 02–????? Filed ??–??–02; 8:45 am]

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